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BEUSSE WOLTER SANKS MORA & MAIRE, P. A.
390 NORTH ORANGE AVENUE
SUITE 2500
ORLANDO, FL 32801

EXAMINER	
WORLEY, CATHY KINGDON	
ART UNIT	**PAPER NUMBER**
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,448	FOGHER ET AL.	
	Examiner	Art Unit	
	Cathy K. Worley	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-51* is/are pending in the application.

4a) Of the above claim(s) *32,33 and 43-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-31,34-42 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction/Election

1. In response to the communication received Oct. 23, 2006 from Joseph Fischer, the election with traverse of group I, claims 23-31,34-42, and 51, is acknowledged. The Applicant traverses on the grounds that the prior art cited by the examiner does not, in fact, teach the expression of a lysosomal enzyme in the seeds of a plant (see Applicant's arguments on pages 5-11 of the response received on Oct. 23, 2006).

The Applicant argues that the prior art document teaches inducible expression in leaves rather than seeds (see page 5 of the response), that the lysosomal enzyme cannot be extracted in an active form from leaf tissue (see pages 6-7 of the response), that the enzyme obtained from tobacco in the prior art document appears to have a different glycosylation pattern compared to the same enzyme expressed in animal cells (see page 9 of the response), that the recitation of a seed in the prior art document does not teach expression of the lysosomal enzyme in the seed (see page 10 of the response), and that the company that attempted to utilize the invention from the prior art document, Croptech, was not successful and filed for bankruptcy in 2003 (see page 11 of the response). These arguments are persuasive with regard to the novelty of the technical feature linking the instant

claims, however, even though the technical feature is novel, it lacks an inventive step (see rejections under 35 USC 103(a), below) and thus does not provide a contribution over the prior art. Therefore, the restriction requirement based on lack of unity of invention is maintained.

Claims 23-51 are pending in the instant application. Claims 32-33 and 43-50 are withdrawn from consideration because they are directed to non-elected inventions.

Claims 23-31, 34-42, and 51 are examined in the present office action.

Specification

2. The use of the trademarks CENTRICON and AMICON has been noted in this application. They should be written in all capital letters wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

3. The specification is objected to for minor informalities. On page 4, in line 12, there is a square symbol between "human" and "-L-iduronidase", this square symbol

should be replaced with the appropriate character. On page 6, in line 36, there is a square symbol between "acid" and "–glucosidase", this square symbol should be replaced with the appropriate character. On page 7, in line 34, there should be a space between "above" and "cited". On page 12, in line 12, there appears to be a symbol between "10" and "μg/well"; this symbol should be deleted and replaced with a space. In addition, on page 12, in line 19, there appears to be a symbol between "15" and "g"; this symbol should be deleted and replaced with a space or with the appropriate character.

4. The abstract of the disclosure is objected to because it is not descriptive enough of the elected invention. The abstract should consist of between 50 and 150 words and should describe essential elements of the invention; for example, expression levels of at least 0.8% total protein.

Claim Objections

5. Claims 23, 26-27, 34, and 37-38 are objected to because of informalities. In light of the specification, the Examiner is able to interpret the claims for the purposes of examination, however, the wording is awkward and technically incorrect in places. If the Applicant makes the changes that are requested, below, these objections will be withdrawn.

Applicant is requested to make the following change to claim 23:

- replace "via the use of" with - - with - - .

Applicant is requested to make the following changes to claims 23 and 34:

- amend part a. to recite - - a promoter that functions in plants to initiate stage-specific transcription in seed storage organs, operably linked to; - -;
- amend part b. to replace "dispatch" with - - target - - ;
- amend part c. to replace "deleted of the" with - - lacking its - - ; and
- amend the last line to replace "at least the 0.8% of the total protein of the seed" with - - at least 0.8% of the seed-extracted total proteins - - (support for this language can be found in the specification on page 27, in line 17).

Applicant is requested to make the following change to claims 26-27 and 37-38:

- replace "and is fused to the sequence encoding the structural portion of the mature lysosomal enzyme deleted of the native signal sequence" with - - and wherein the DNA sequence encoding the signal sequence is fused in-frame to the sequence encoding the structural portion of the mature lysosomal enzyme lacking its native signal sequence - - (support for this can be found in the specification on page 18 in the first paragraph which describes the construction of a plasmid).

Claim Rejections - 35 USC § 112 and 101

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51 provides for the use of a seed of a genetically modified plant, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 51 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

7. Claims 23-31, 34-42, and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. All dependent claims are included in these rejections.

The claims are broadly drawn to a transformed plant that comprises an expression vector comprising a "stage-specific" promoter, a signal sequence able to dispatch an enzyme to seed storage organs and to provide the post-translational modifications required for enzymatic activity, and a sequence encoding a lysosomal enzyme; including embodiments wherein the promoter and signal sequence can be taken from "a 7S soy globulin gene" or can be "a functional equivalent" thereof.

The Applicants describe a plant expression cassette comprising a promoter of the basic 7S soy globulin gene which they refer to as PGLOB and describe as SEQ ID NO:6 (see page 18, lines 2-3), and they describe a nucleic acid encoding a signal sequence from the basic 7S soy globulin (SEQ ID NO:7) (see page 18, lines 3-5). They describe plasmids comprising an expression cassette comprising this promoter operably linked to a polynucleotide encoding this signal sequence fused to glucocerebrosidase (see pages 20-21 and figures 1-3). They describe transgenic tobacco plants transformed with this expression cassette (see pages 22-23). They also describe a plasmid comprising an expression cassette comprising this promoter

operably linked to a polynucleotide encoding this signal sequence fused to α-galactosidase A (see pages 27-28 and figure 4); and transgenic tobacco plants transformed with this plasmid (see page 28, lines 11-17). They also describe a plasmid comprising an expression cassette comprising this promoter operably linked to a polynucleotide encoding this signal sequence fused to α-glucosidase A (see pages 28-19 and figure 5).

The Applicants do not describe any promoters other than SEQ ID NO:6; they do not describe any nucleic acids encoding signal sequences other than SEQ ID NO:7. They do not describe any "functional equivalents" of SEQ ID NO:6 or SEQ ID NO:7.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F. 3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The prior art teaches that the 7S globulin from soybean is also referred to as β-conglycinin (see Hayashi et al. (1998) MGG, Vol. 258, pp. 208-214, abstract). The prior art teaches that this protein is comprised of three subunits; α', α, and β (see

Chen et al. (1989) Developmental Genetics, Vol. 10, pp. 112-122, abstract). Chen et al. teach that both the α'and β subunits accumulated during mid-to-late stages of seed development (see abstract).

In the instant claims, the recitation of "stage-specific" does not further limit the claims, because no specific stage is recited. The recitation of "a 7S soy globulin gene promoter" encompasses any sequence located upstream of the coding region of any of the α', α, and β genes. The recitation of "or a functional equivalent" encompasses any seed-specific promoter. The recitation of "a 7S soy globulin signal sequence" encompasses a signal sequence from any of the α', α, and β genes. The recitation of "or a functional equivalent" encompasses any signal sequence from any plant gene that is able to target the enzyme to seed storage organs and provide the post-translational modifications required for enzymatic activity.

However, the instant specification describes only one promoter, that of SEQ ID NO:6. The instant specification describes only one signal sequence, that encoded by SEQ ID NO:7. The only promoter described in the instant specification is active during mid-to-late stages of seed development, as evidenced by the teachings of Chen et al. (see abstract).

The Applicants fail to describe a representative number of 7S soy globulin gene promoters or functional equivalents, or 7S soy globulin signal sequences or functional equivalents, or stage-specific promoters. The Applicants only describe the promoter of SEQ ID NO:6 which is active during the mid-to-late stages of seed

development and the signal sequence encoded by SEQ ID NO:7. Furthermore, the Applicants fail to describe structural features common to members of the claimed genus of promoters and claimed genus of signal sequences. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for stage-specific expression in seeds or for correct protein targeting and post-translational modifications, it remains unclear what features identify promoters and signal sequences capable of such activity. Since the genus of promoters and genus of signal sequences have not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

8. Claims 23-31, 34-42, and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant transformed with the promoter of SEQ ID NO:7 operably linked to the polynucleotide of SEQ ID NO:6 and a polynucleotide encoding a lysosomal enzyme, does not reasonably provide enablement for a transformed plant that comprises an expression vector comprising any "stage-specific" promoter, any signal sequence able to dispatch an enzyme to seed storage organs and to provide the post-translational modifications required for enzymatic activity, and a sequence encoding a lysosomal enzyme. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are broadly drawn to a transformed plant that comprises an expression vector comprising a "stage-specific" promoter, a signal sequence able to dispatch an enzyme to seed storage organs and to provide the post-translational modifications required for enzymatic activity, and a sequence encoding a lysosomal enzyme; including embodiments wherein the promoter and signal sequence can be taken from "a 7S soy globulin gene" or can be "a functional equivalent" thereof.

Applicants teach a plant expression cassette comprising a promoter of the basic 7S soy globulin gene which they refer to as PGLOB and describe as SEQ ID NO:6 (see page 18, lines 2-3), and they teach a nucleic acid encoding a signal sequence from the basic 7S soy globulin (SEQ ID NO:7) (see page 18, lines 3-5).

They teach plasmids comprising an expression cassette comprising this promoter operably linked to a polynucleotide encoding this signal sequence fused to glucocerebrosidase (see pages 20-21 and figures 1-3). They teach transgenic tobacco plants transformed with this expression cassette (see pages 22-23). They also teach a plasmid comprising an expression cassette comprising this promoter operably linked to a polynucleotide encoding this signal sequence fused to α-galactosidase A (see pages 27-28 and figure 4); and transgenic tobacco plants transformed with this plasmid (see page 28, lines 11-17). They also teach a plasmid comprising an expression cassette comprising this promoter operably linked to a polynucleotide encoding this signal sequence fused to α-glucosidase A (see pages 28-19 and figure 5).

Applicants do not teach any promoters other than SEQ ID NO:6; they do not teach any nucleic acids encoding signal sequences other than SEQ ID NO:7. They do not teach any "functional equivalents" of SEQ ID NO:6 or SEQ ID NO:7.

The prior art teaches that the 7S globulin from soybean is also referred to as β-conglycinin (see Hayashi et al. (1998) MGG, Vol. 258, pp. 208-214, abstract). The prior art teaches that this protein is comprised of three subunits; α', α, and β (see Chen et al. (1989) Developmental Genetics, Vol. 10, pp. 112-122, abstract). Chen et al. teach that both the α'and β subunits accumulated during mid-to-late stages of seed development (see abstract).

In the instant claims, the recitation of "stage-specific" does not further limit the claims, because no specific stage is recited. The recitation of "a 7S soy globulin gene promoter" encompasses any sequence located upstream of the coding region of any of the α', α, and β genes. The recitation of "or a functional equivalent" encompasses any seed-specific promoter. The recitation of "a 7S soy globulin signal sequence" encompasses a signal sequence from any of the α', α, and β genes. The recitation of "or a functional equivalent" encompasses any signal sequence from any plant gene that is able to target the enzyme to seed storage organs and provide the post-translational modifications required for enzymatic activity.

Given the lack of guidance in the instant specification, undue trial and error experimentation would be required for one of skill in the art to determine which polynucleotide fragments located upstream of the coding region of any of the α', α, and β genes would have seed-specific promoter activity. It would require even more undue trial and error experimentation to screen through all possible nucleic acid molecules to identify a "functional equivalent" to these promoters. Undue trial and error experimentation would also be required to determine what signal sequences provide the function of "dispatching" a lysosomal enzyme to seed storage organs and providing unspecified post-translational modifications required for the expression of the lysosomal enzyme in active form.

With regard to the promoters encompassed by the instant claims, deletion analysis of various promoters have shown that even DNA segments from the

portion of a promoter region containing sequence elements thought to be most important (*e.g.*, the TATA-box) need to have sufficient length and comprise additional sequences. Maiti et al (1997, Transgen. Res., 6:143-156), in studies on a figwort mosaic virus promoter, found that the smallest portion upstream of the transcriptional start site of that would support transcription was 198 basepairs long; segments of 73 and 37 basepairs did not work (Fig. 4). Doelling et al (1995, Plant J. 8:683-692) found that the minimal rRNA promoter of *Arabidopsis thaliana* is at least 33 nucleotides long (Fig. 1). Therefore the prior art teaches that there is a high degree of unpredictability with regard to the minimal length of the sequences upstream of a coding region that is required for promoter activity.

In the instant invention, the promoter is required to express in seed storage organs and to be "stage-specific". The prior art teaches that the region of a given promoter that has a specific activity cannot be predicted and involves the complex interaction of different subdomains (Benfrey et al, 1990, Science 250:959-966, see Abstract, Fig. 3-5). Even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (Kim et al, 1994, Plant Mol. Biol. 24:105-117, Tables 1-4, Abstract, Fig. 1-2).

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to make the claimed invention,

and therefore, the invention is not enabled throughout the broad scope of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 23-31, 34-42, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radin et al. (US Patent No. 5,929,304, issued on Jul. 27, 1999) in view of Chen et al. (Developmental Genetics (1989) Vol. 10, pp. 112-122), and further in view of Whitelam GC (J. Sci. Food Agric. (1995) Vol. 68, pp. 1-9).

The claims are drawn to a transformed plant that comprises an expression vector comprising a "stage-specific" promoter, a signal sequence able to dispatch an enzyme to seed storage organs and to provide the post-translational modifications required for enzymatic activity, and a sequence encoding a lysosomal enzyme; including embodiments wherein the promoter and signal sequence can be taken from "a 7S soy globulin gene" or can be "a functional equivalent" thereof.

Radin et al. teach plants transformed with a recombinant expression construct encoding a lysosomal enzyme (see claim 33). They teach the production of

enzymatically active recombinant lysosomal enzymes of both human and animal origin (see abstract). They teach the use of several different signal peptides (see column 14, lines 31-67 and column 15, lines 1-9). They teach the removal of the signal peptide (see column 14, lines 33). They teach expression vectors that are plasmids (see column 22, line 1). Rabin et al. teach plants expressing any one of a list of lysosomal enzymes (see claims 26, 27, 47, and 48), and this list includes glucocerebrosidase, which is recited in the instant claims and reduced to practice in the instant application. They specifically teach transgenic tobacco plants expressing a lysosomal enzyme (see columns 21-25). They teach a seed of such a plant (see claims 54-57).

Radin et al. do not teach a promoter of a plant gene specific for the expression in seed storage organs and stage-specific, nor do they teach expression in an amount of at least 0.8% of total proteins of the seed, nor do they teach a promoter from a 7S soy globulin gene or a signal sequence from a 7S soy globulin protein.

Chen et al. teach constructs comprising different fragments of the promoter from the α' subunit gene (which is a 7S globulin protein) (see page 117, Figure 3; and page 116, right column). The α' subunit promoter is a seed-specific promoter that function during the mid-to-late stages of seed development (see page 112, right column, first two lines). They teach that transgenic plants utilizing the α' subunit promoter to express α' subunit protein produced seeds in which the recombinant protein accumulated to between 0.1% and 5% of the proteins extracted from the

seeds (see page 114, right column). This recombinant α' subunit protein comprises its own native signal sequence which is a 7S soy globulin signal sequence. Chen et al. also utilized a 170-bp fragment of the α' subunit promoter to drive expression of the chloramphenicol acetyltransferase (CAT) reporter gene (see paragraph bridging pages 116-117).

At the time the invention was made, it would have been obvious and within the scope of one of ordinary skill in the art to modify the plants taught by Radin et al. to utilize the α' subunit promoter taught by Chen et al. One would have been motivated to do so because Whitelam teaches that expression of valuable recombinant enzymes in seeds is desirable because the recombinant enzymes can be stored for long periods in dry seeds (see page 8, second paragraph). Whitelam teaches that the seed-expression system can be manipulated by utilizing oleosin fusions to provide cost-effective protein purification from the bulk of seed proteins (see paragraph bridging pages 7-8). Whitelam discusses "bio-farming" in general (see abstract and page 2, second paragraph), and specifically teaches that there are advantages to seed-localized expression of recombinant proteins (see page 2, right column). Given the successes and advantages of expressing recombinant enzymes in seeds, taught by Whitelam, one would expect to succeed in expressing the lysosomal enzymes taught by Radin in seeds. One would have been motivated to utilize the α' subunit promoter taught by Chen et al. because they teach that they

achieved a dramatic enhancement of expression (25- to 40- fold) compared to expression with the 35S promoter (see page 117, first paragraph).

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cathy K. Worley whose telephone number is (571) 272-8784. The examiner is on a variable schedule but can normally be reached on M-F 10:00 - 4:00 with additional variable hours before 10:00 and after 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER